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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,294	09/29/2003	Thomas L. Cantor	532212001900	5531

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,294	CANTOR ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Applicant's amendment filed on 9/17/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 6-7 and 9 had been cancelled.

2. Currently, claims 1-5, 8, 10-15 are under examination. Claims 16-24 are withdrawn from further consideration.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. Applicant recites claim 1 "A parathyroid hormone (PTH) assay control, comprising a composition having a known concentration of a whole PTH component mixed with known concentration of a PTH fragment component". It is noted no "mixed with" term in the specification. See 37 CFR 1.75 (d)(1) and MPEP Section 608.01 (o). Correction is required.

Claim Rejections - 35 USC § 112

Scope of Enablement

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5, 8, 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for epitope peptide comprising at least 4 amino acid residues

length , does not reasonably provide enablement for three amino acid length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The instant invention recites a PTH assay control, comprising two main substances, i.e. a known concentration of whole PTH mixed with a known concentration of PTH fragment component. It has been established that the cross-reactivity of PTH immunoassay reagents and related interfering factors , e.g. PTH fragment components, have resulted in inaccuracies in PTH level assessments. Frequently, traditional PTH level assessments may not be aware of the discrepancies between actual and measured PTH levels in subjects. As the sensitivity of PTH assays is very important for treatment decisions in subjects, the instant assay control can provide monitoring, and adjusting of PTH assay results to obtain a reliable indicator of actual PTH levels in a subject.

Applicant develops specific antibody recognizing the whole PTH while avoid interact with the non-PTH (1-84) fragments, including the amino acid position from 2 to 33 of the N-terminal of PTH, and the positions of 35 to 84 of the PTH. However, applicant also recites the feature that "the PTH fragment has a minimal length of three amino acid residues" (See claim 1, step (b)). The length of the limited amino acid here may impose undue experimentation to one ordinary skill in the art. However, according to Geysen et al. (J. Mol Recognition 1988, Vol. 1, page 32), amino acid replaceability for the epitopes of the antigen to bind antibody is a common

problem for specificity. Geysen et al. show that on average about 4-5 amino acid residues in epitopes are required to determine the specificity and provide binding energy (See Abstract). Furthermore, Lerner et al. indicate that antibody epitope may be as small as 6-15 shared amino acid residues (See Nature 1982, Vol. 299, page 592-596). Based on the general practice in the field, using only 3 amino acid residues as the epitope would not generate a reliable "predictable result" for the purported goal, i.e. control for monitoring PTH assay.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 8, the "shelf-life" lacks antecedent basis.

With respect to claim 8, it is not clear what does it mean "shelf-life". What it refers to, e.g. activity or half-life? Applicant is invited to point the support for this term.

With respect to claim 12, line 2, it is not clear what the "PTH component" refers to. Does it mean "whole PTH component", or "PTH fragment component".

With respect to claim 14, it suffers the same problem as claim 12. Applicant needs to clarify.

Response to Applicant's Arguments

5. The rejections of claims 1-3, 8, 10-15 under 35 U.S.C. 103(a) as being unpatentable over Gao et al. in view of Holthuis et al. are withdrawn because none of the references teaches a composition comprising a known concentration of whole PTH *mixed with* a known concentration of PTH fragments (emphasis added). The main reference Gao et al. merely using both whole PTH and PTH fragment is a separate manner, i.e. no mixture, to conduct conventional PTH assay.

6. Similarly the rejections of claims 1-3, 8, 11-15 under 35 U.S.C. 103(a) as being unpatentable over Bouillon et al. in view of Holthuis et al. are withdrawn because none of the references teaches a composition comprising a known concentration of whole PTH *mixed with* a known concentration of PTH fragments (emphasis added). The main reference Bouillon et al. merely using both whole PTH and PTH fragment is a separate manner, i.e. no mixture, to conduct conventional PTH.

7. Applicant's arguments with respect to claims 1-5, 8, 10-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

November 20, 2007

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